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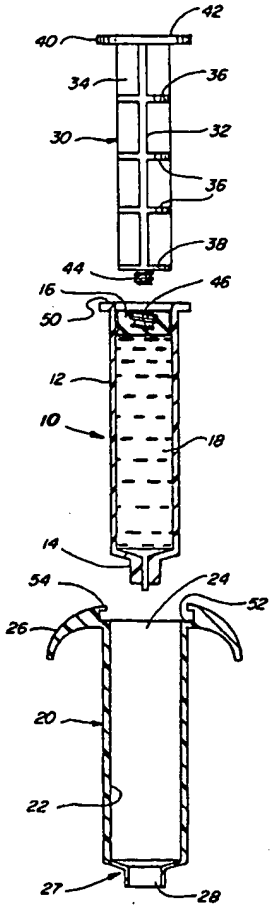
(54) Title: PREFILLED DELIVERY APPARATUS ADAPTED FOR STERILE USE

(57) Abstract

A prefilled delivery apparatus adapted for sterile use without contamination from the exterior of the apparatus. The apparatus includes a prefilled syringe assembly (10) with sterile contents (18) and includes also a sterile sleeve member (20) having a sterile exterior surface (20) and an interior surface (22) adapted to receive the syringe (10). The prefilled syringe assembly is receivable within the sleeve member (20) to provide a delivery apparatus having a sterile exterior that can be handled in a sterile environment without contamination from the exterior of the prefilled syringe.



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PREFILLED DELIVERY APPARATUS ADAPTED FOR STERILE USE

Field of the Invention

The present invention relates to prefilled delivery apparatus and devices such as syringes and the like used by physicians and other medical personnel for delivery of various media such as fluids in the form of liquids or gases, or fluids comprising or containing pharmaceutical media. More specifically, the present invention relates to delivery apparatus of the aforementioned type which are capable of being handled without contamination from the exterior surfaces thereof in a totally sterile environment.

Description of the Prior Art

Prefilled delivery apparatus such as prefilled syringes and the like are known in the art for use in various medical applications. In such apparatus, the syringe is prefilled with the medium which is to be dispensed and the entire assembly, including the syringe and its contents, is then sterilized and supplied for end use. Prefilled, sterile syringes of this type are disclosed, for example, In U.S. Patents 4,628,969 - Jurgens, Jr. et al., and 4,718,463 - Jurgens, Jr. et al.

While the syringe and its contents are initially in a sterile condition, the exterior portions thereof may become contaminated in the process of handling by physicians or attending medical personnel before reaching the point of end use. The later handling of such contaminated exterior portions of such prefilled syringes by physicians who are carrying out procedures in completely sterile environments thus presents a serious risk of contamination.

It is accordingly an object of the present invention to provide a prefilled delivery apparatus, which has been sterilized at the point of manufacture thereof, and which is adapted for end use in a manner which avoids the risk of contamination from the exterior surfaces thereof in the process of handling thereof at the point of end use.

Summary of the Invention

In accordance with one embodiment of the present invention, a prefilled delivery apparatus is provided which includes a sterile, prefilled syringe assembly along with a sterile sleeve member and a sterile push rod member, with the syringe assembly, the sleeve member and the push rod member being adapted for assembly at the point of end use in a manner which enables the end use of the assembly so formed to be effected without contamination from the exterior portions of the syringe assembly.

Brief Description of the Drawings

Fig. 1 is an exploded, cross-sectional view of the elements of a delivery apparatus embodying the present invention; and

Fig. 2 is a cross-sectional view of the elements of the delivery apparatus of Fig. 1 as assembled for end use.

Detailed Description of the Preferred Embodiments

Referring now to the embodiment of Fig. 1, there is shown a prefilled and presterilized syringe assembly 10 which is formed of a container 12, a sealed tip portion 14 and a piston element 16 positioned within the container 12 to form an internal storage volume for a stored medium 18. The syringe assembly 10 is similar to the prefilled and pre-sterilized syringe elements of the prior art such as those described above and may be prepared, for example, in a manner as described in the U.S. Patents mentioned above, assigned to the same assignee as the present application, the subject matter of which patents is incorporated herein by reference, so as to provide a completely sterile assembly as supplied for end use.

The delivery apparatus of the embodiment of Fig. 1 also includes a hollow sleeve member 20 shaped to receive assembly 10. The sleeve 20 is preferably cylindrical and is formed with an interior surface 22 having a diameter adapted to receive through open end 24 thereof, in a sliding but preferably snug fit, the external diameter of the container 12 of the prefilled syringe assembly 10 when the container 12 is inserted through the open end 24. The sleeve member 20 is provided with an exterior flange 26 which is flared away from open end 24 and which forms an interface and barrier from contamination thus accommodating the use of the apparatus as will be explained below in detail. A lip 54 is provided on the flange 26 at an edge

At delivery end 27 of sleeve member 20 opposite open end 24 there is formed an outlet opening 28 which is adapted to receive the sealed tip 14 of syringe assembly 10 when assembly 10 is inserted into sleeve member 20. Outlet opening 28 is preferably shaped to substantially conform to the sealed tip 14 of syringe assembly 10 and is dimensioned to allow the sealed tip 14 of the syringe assembly 10 to protrude slightly from opening 28 when assembly 10 is inserted into sleeve member 20.

The embodiment of Fig. 1 also includes a push rod element 30 which may be formed by any suitable construction such as, but not limited to, elongated, flat, planar portions 32 and 34 arranged perpendicular to each other together with reinforcing ribs 36 and end cap elements 38 and 40. The end cap element 40 is provided with a flat surface 42 for permitting engagement with the fingers of an operator for exerting a pushing force on the push rod 30.

Formed integrally with the end cap element 38, or optionally formed separately and attached thereto, is suitable means for connecting push rod 30 to piston 16 such as, but not limited to, a threaded portion 44 adapted to engage a threaded socket 46 in piston 16 of the assembly 10.

The sleeve member 20 and the push rod member 30 are also both sterilized and provided in aseptic condition as components of the embodiment of Fig. 1. The sleeve member 20 and the push rod 30 are maintained in a sterile condition and are preferably stored separately from the syringe assembly 10. Thus, although the exterior portions of the syringe assembly 10 may become contaminated in the course of handling prior to reaching the point of end use, the sleeve

10 may become contaminated in the course of handling prior to reaching the point of end use, the sleeve member 20 and the push rod 30, which are supplied for use with the syringe assembly 10, are maintained in a sterile condition to the point of end use and assembly thereof with the syringe assembly 10 in a manner which will now be described.

Referring now to Fig. 2, there is shown an assembly of the elements shown in the exploded view of Fig. 1. The assembled embodiment of the invention is preferably formed by first assembling the push rod element 30 and the syringe assembly 10 by engaging the threaded portion 44 of the push rod with the socket 46 of the piston 16. The sub-assembly of the push rod 40 and the syringe assembly 10 is then inserted into the sleeve member 20 by manually grasping the push rod 30 and using the same to make the insertion.

The sub-assembly of the push rod 30 and the syringe assembly 10 is inserted into the sleeve member 20 until an end flange 50 on the container 12 engages a recessed portion 52 on the sleeve member 20, at which point the sealed tip portion 14 protrudes from the outlet opening 28. The sleeve member 20 has means for locking the syringe assembly 10 in this position. An example of such means is illustrated in Fig. 2 wherein the sleeve member 20 has a lip 54 which extends from the flange 26 and overlies the recess 52. This lip 54 engages the end flange 50 formed on the container 12 in a "snap-fit" manner to lock the syringe assembly 10 within the sleeve member 20. In forming the assembly as just described, it is not necessary to make any contact by a human hand with the external surface of the syringe assembly 10. The assembly so formed as

illustrated in Fig. 2 is then ready for use by the physician or attending medical personnel.

In order to use the assembly shown in Fig. 2, the sleeve member 20 may be grasped in the hand with the sleeve member 20 preventing any contact between the hand and the external surface of the syringe assembly 10 and flange 26 forming an interfacing barrier to prevent any contact by the hand with the rear flange 50 of the syringe assembly 10. In this manner, flange 26 performs a shielding function insofar as it prevents contact by the hand with the rear flange 50 of the syringe assembly 10. As seen in Fig. 2, rear flange 50 of the syringe assembly 10 is not completely covered by the sterile sleeve member 20, yet contact with the exposed part of flange 50 by the hand is prevented by the aforementioned shielding function of the sleeve member 20. After the sealed tip 14 is opened, the push rod 30 may then be operated by applying pressure on the cap element 40 to expel the fluid 18 from the interior of the container 12.

Assembling the elements of the apparatus of Fig. 1 to form the assembly of Fig. 2 in the manner just described thus enables and accommodates the use and operation of the prefilled and pre-sterilized syringe assembly 10 in a manner which avoids any contact with the possibly contaminated external surfaces of the syringe assembly 10. That is, the assembly of Fig. 2 can be handled by a "gloved" physician in a totally sterile environment without any contact with the possibly contaminated exterior surfaces of the syringe assembly 10.

As noted above, the pre-sterilized sleeve member 20 and the pre-sterilized push rod 30 are preferably packaged separately from the syringe assembly 10 so as

the syringe assembly 10 may be freely handled without fear of contaminating the exterior surfaces thereof because, when the assembly of Fig. 2 is formed from the components of the invention illustrated in the embodiment of Fig. 1, the exterior surfaces of the syringe assembly 10 are completely shielded and protected against any contact and, at the same time, full use of the assembly is facilitated by the sterile sleeve member 20 and the sterile push rod 30.

While the present invention and the embodiments presented herein have been set forth and described in detail for the purposes of making a full and complete disclosure of the subject matter thereof, the disclosure herein presented is not intended to be limiting in any way with respect to the true scope of this invention as the same is set forth in the appended claims.

What is claimed is:

1. A delivery apparatus comprising, in combination:

a syringe assembly having a container with a sealed tip portion at one end thereof and a piston near the opposite end thereof, and a fluid medium stored within said container between said piston and said sealed tip portion, said piston being slidably mounted within said container for expelling said fluid medium through said tip portion when said tip portion is unsealed;

an aseptically sterile push rod member connectible to said piston for engaging said piston to enable movement thereof within said container; and

an aseptically sterile sleeve member formed and adapted to receive said container of said syringe assembly to accommodate the insertion of said syringe assembly into said sleeve member and for shielding the exterior surface of said container when said syringe assembly is so inserted into said sleeve member ;

said sleeve member including an opening at one end thereof for accommodating the insertion of said container through said opening and a tip opening at the opposite end thereof for accommodating the protrusion of said sealed tip portion when said syringe assembly is inserted into said sleeve member;

whereby the assembled combination formed when said push rod member is connected to said piston and said syringe assembly is inserted into said sleeve member provides an aseptically sterile assembly which can be grasped at the exterior of said sleeve member and operated by means of said push rod member without contact with the exterior surfaces of said syringe assembly.

2. A delivery apparatus as claimed in claim 1, wherein said sleeve member has means for locking said syringe assembly within the sleeve member.

3. A delivery apparatus as claimed in claim 2, wherein said locking means comprises a lip formed on said sleeve member near said open end for engaging said container.

4. A delivery apparatus as claimed in claim 1, wherein said sleeve member includes barrier means for preventing contact with said container when handling the exterior of said sleeve member.

5. A delivery apparatus as claimed in claim 4, wherein said barrier means comprises a flange formed near the open end of said sleeve member.

6. A delivery apparatus as claimed in claim 1, wherein the tip opening of said sleeve member is shaped to substantially conform to and surround the sealed tip portion of said container of said syringe assembly.

7. A delivery apparatus comprising:

a syringe assembly having a container with a sealed tip portion at one end thereof and a piston near the opposite end thereof, and a fluid medium stored within said container between said piston and said sealed tip portion, said piston being slidably mounted within said container for expelling said fluid medium through said tip portion when said tip portion is unsealed;

an aseptically sterile push rod member connected to said piston for moving the piston within said container; and

an aseptically sterile sleeve member having a cylindrical interior surface formed therein, said container of said syringe assembly being positioned in said sleeve member within said cylindrical interior surface with said sleeve member shielding the exterior surface of said container;

said sleeve member including an opening at one end thereof for accommodating the insertion of said container into said sleeve member and a tip opening opposite said opening through which said sealed tip portion protrudes;

whereby said delivery device provides an aseptically sterile assembly which can be grasped and operated by means of said push rod member without contact with exterior surfaces of said syringe assembly.

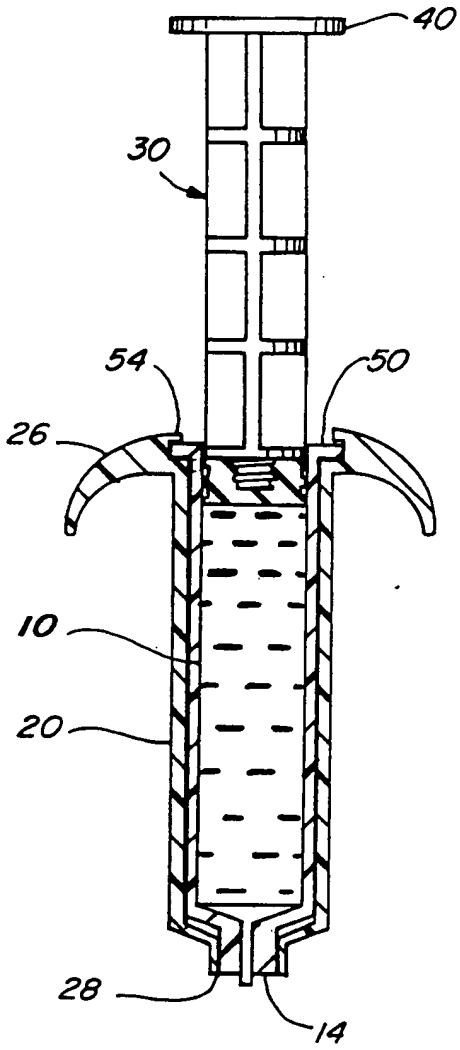
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Fig. 2

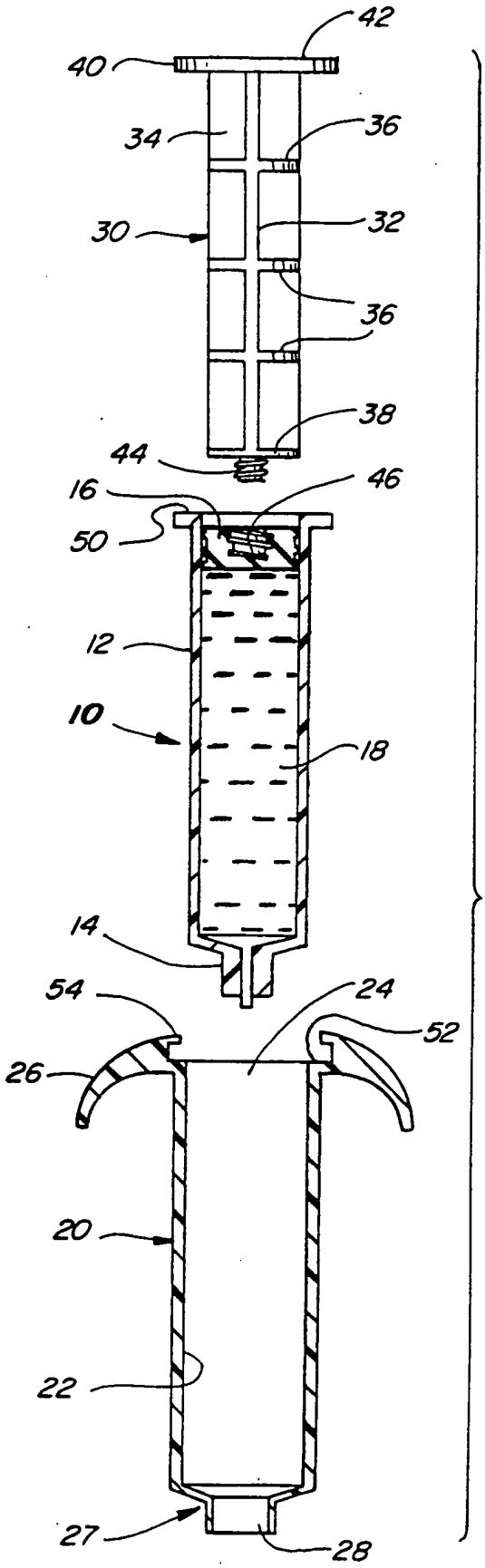
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Fig. 1

INTERNATIONAL SEARCH REPORT

PCT/US93/12030

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/32

US CL :604/199

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/199, 110, 187, 218, 220, 232, 236; 600/5; 128/919

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,976,069, (Ong), 24 August 1976. See entire document.	1-7
Y	US, A, 3,820,541, (Langan), 28 June 1974. See entire document.	1-7
Y	US, A, 2,720,880, (S. V. Whitaker et al), 18 October 1955. Note lip locking means.	3
Y	US, A, 4,628,969, (Jurgens, Jr et al.), 16 December 1986. See discussion of syringe sterilization	1-7
Y	US, A, 4,718,463, (Jurgens, Jr. et al.), 12 January 1988. See discussion of syringe sterilization.	1-7

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,401,108, (Galkin et al.), 30 August 1983. Note length of sleeve.	6